

Remarks

This Response is filed in reply to the non-final Office Action of October 25, 2004, in which claims 1, 3, 6, and 8-11 were rejected under 35 U.S.C. §§ 102 and 103. No amendments are made to the claims with this Response. Claims 1, 3, 6, and 8-11 are pending.

Applicants note that the Office Action of October 25, 2004 does not comment on the applicants' previous amendments and arguments set forth in their Response dated October 4, 2004, other than that they have been entered. Applicants thus consider the previous Office Action rejections as having been overcome, particularly in view of the new grounds for rejection set forth in the current Office Action.

The Office Action

The Office Action rejects claims 1, 3, and 6 under 35 U.S.C. § 102(b) as anticipated by Daneshvar (U.S. Patent No. 5,263,966). The Office Action also rejects claim 1 under 35 U.S.C. § 102(b) as anticipated by Flam et al. (U.S. Patent No. 4,041,948). Claims 8-11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Flam et al. because it is well-known in the art to make an adsorbent material from fabric comprised of a gel-forming absorbent composition.

Lack of Anticipation

To anticipate a claim, a reference must teach every element of that claim. That is, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See, M.P.E.P. § 2131.

Daneshvar, U.S. Patent No. 5,263,966

Daneshvar does not teach anything that is inserted anywhere. It is not even analogous art. It is directed to a wrap which covers the outside of the groin area of a patient and supports a specially shaped pressure balloon when the balloon is inflated. The device comprises a main wrap, preferably from a tough synthetic fabric, which wraps around both the lower abdomen and the upper thighs to give support for the application of pressure to the groin by a specially shaped inflatable balloon contained within the wrap. Col. 1, lines 45-50. The wrap of Daneshvar is thus for external applications only.

In contradistinction, claim 1 recites "a device for controlling bleeding on an inner wall of a body cavity or passageway, comprising an insertable shaft...." The claimed invention is thus for internal application into a body cavity or passageway. Daneshvar does not disclose such a use. Therefore, the elements of the pending claims are neither disclosed nor suggested by Daneshvar. Applicants submit claim 1 is in a condition for allowance and respectfully request withdrawal of the rejection.

Because claims 3 and 6 depend ultimately from claim 1, they too are in condition for allowance for at least this reason.

Flam et al., U.S. Patent No. 4,041,948

Flam et al. is directed to a digital tampon having a rigidifying element that has a dry resistance to compression sufficiently high enough to allow insertion and a wet resistance to compression, which is less than the dry resistance, and sufficiently low enough to allow the tampon to expand when wet and still be comfortable in use and during removal. Flam et al. discloses that in addition to the constraints of rigidity and size, the tampon must be able to capture, i.e., absorb, entrap and/or retain, a sufficient quantity of menses. See col. 1, lines 25-28. To accomplish this, at col. 7, lines 3-18, Flam et al. discloses an embodiment of a tampon having a first absorbent 86 and a second absorbent 88 enclosed by a pervious cover 90.

In complete contrast, claim 1 of the present invention requires a device for controlling bleeding and having a hemostatic shroud disposed around an inner component. The term hemostatic is attributed a definition that would be known to one of ordinary skill in the art. Webster's New Twentieth Century Dictionary defines haemostatic as "capable of stopping the flow of blood." A copy of the definition is enclosed. The current specification emphasizes the hemostatic qualities of the shroud at page 6, line 20 to page 7, line 12, stating that the hemostatic agent refers to any agent or material that is capable of arresting, stemming, or preventing bleeding. In use, the shroud-covered balloon catheter is inflated to press the hemostatic shroud fabric against a cavity wall. Through pressure and contact with the hemostatic agent, bleeding is stopped.

Flam et al. neither discloses nor suggests stopping the flow of menses by applying pressure to a hemostatic shroud placed against a body cavity. Moreover, applicants submit that an interpretation of the tampon in Flam et al. as having hemostatic qualities is repugnant to its entire purpose. A tampon that stimulates the clotting of the menses would negatively effect the health of the tampon user. An interpretation or modification of the prior art that would render the prior art being modified unsatisfactory for its intended purpose, cannot anticipate each and every limitation of the claimed invention. Reconsideration of the rejection is respectfully requested.

Non obviousness

Claims 8-11 depend either directly or indirectly from independent claim 1. Because claims 8-11 are considered more narrow from the claims from which they depend, and claim 1 was not rejected as obvious in view of Flam et al., applicants submit that claims 8-11 are also in condition for allowance.

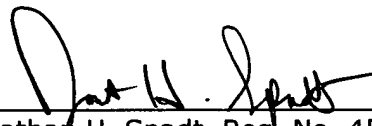
Notwithstanding the above reason for the allowability of claims 8-11, applicants offer the following remarks in response to the rejection.

Applicants challenge the Office Action statements that "it is well known in the art to [make] absorbent material from fabric comprised [of] a gel-forming absorbent composition" and that it would be obvious to "substitute the hemostatic material or absorbent material of Flam et al. for the material as claimed." A general conclusion of what is well-known or what are common substitutes to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection. See *Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001).

Conclusion

For the reasons stated above, claims 1, 3, 6, 8, and 9-11 are believed to be in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,



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Enclosure: Webster's Definition (3 pgs.)

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